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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,266	07/09/2003	Andrea Leone-Bay	01946/100B035-USC	2422

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,266	LEONE-BAY ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 0203* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The status of parent application 10/142,009 needs to be updated in the priority claim inserted at page 1, lines 8-14, of the specification by the preliminary amendment filed July 9, 2003. Correction is required.

2. Claims 40, 43, 66, 68-73, 76, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "said mixture of mucopolysaccharides" in claim 40. It is believed that claim 40 should instead depend upon claim 38. Because of the dependency of claim 43, it appears that Applicants are claiming a combination of insulin and low molecular weight heparin. It is not clear that this is what was intended by Applicants. It may be that claim 43 should instead depend upon claim 41. There is no antecedent basis in the claims for the phrase "said polysaccharides" in claim 66. It is believed that claim 66 should instead depend upon claim 65. The preamble to claim 68 indicates that a biologically-active agent is to be administered, but the composition which is to be administered, as defined in claim 32, is not limited to biologically-active agents but is drawn to active agents in general. Accordingly, it is not clear whether claim 68 requires the administration of biologically-active agents or whether it embraces the administration of active agents in general.

3. Claims 30, 41, 57, and 67 are objected to because of the following informalities: Claim 30 does not end with a period. In claims 41, 57, and 67, "growth releasing hormones" and "growth hormone-releasing hormones" are synonyms. One of the two should be deleted from each claim. Appropriate correction is required.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 30-36, 39, 41, 42, 47, 51, 52, 54, 57, 59, 63, 64, 67, 68, 70, and 71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,693,073. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '073 patent claims co-administration of insulin and a carrier having the formula recited in claim 3. The '073 patent specifically claims a carrier in claim 6 which differs from Applicants' claimed compound only in the isomerism of the alkanoic acid group, i.e. 2-methylethanoic vs. propanoic. The '073 patent's claimed generic formula embraces compounds having propanoic acid groups (see claim 3, column 21, line 42). It would have been obvious to one of ordinary skill in the art to form the claimed compositions of the '073 patent using a carrier having Applicants' claimed structure because Applicants' claimed compound is encompassed within the claimed formula of the '073 patent; because Applicants' claimed compound is an isomer of the carrier specifically claimed by the '073 patent differing only in the arrangement of the carbon atoms of the alkanoic acid chain; and because Applicants' claimed compound is used to aid in the administration of the same type of drug claimed by the '073 patent. The '073 patent does not claim administering the insulin and the carrier in combination with an excipient, diluent, or dosing vehicle. It would have been obvious to one of

ordinary skill in the art to administer the insulin and the carrier claimed in the '073 patent in combination with an excipient, diluent, or dosing vehicle because excipients, diluents, and dosing vehicles are routinely used in the administration of therapeutic agents for ease of storage, transport, measurement, and administration.

6. Claims 30-47, 51-68, 70, and 71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,440,929. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '929 patent claims co-administration of Applicants' claimed active agents and a carrier having the formula recited in claim 8. The '929 patent specifically claims a carrier in claim 12 which differs from Applicants' claimed compound only in the isomerism of the alkanoic acid group, i.e. 2-methylethanoic vs. propanoic. The '929 patent's claimed generic formula embraces compounds having propanoic acid groups (see claim 8, column 23, line 36). It would have been obvious to one of ordinary skill in the art to form the claimed compositions of the '929 patent using a carrier having Applicants' claimed structure because Applicants' claimed compound is encompassed within the claimed formula of the '929 patent; because Applicants' claimed compound is an isomer of the carrier specifically claimed by the '929 patent differing only in the arrangement of the carbon atoms of the alkanoic acid chain; and because Applicants' claimed compound is used to aid in the administration of the same types of active agents claimed by the '929 patent. The '929 patent does not claim administering the active agents and the carrier in combination with an excipient, diluent, or dosing vehicle. It would have been obvious to one of ordinary skill in the art to administer the active agents and the carrier claimed in the '929 patent in combination with an excipient, diluent, or dosing vehicle because excipients,

diluents, and dosing vehicles are routinely used in the administration of therapeutic agents for ease of storage, transport, measurement, and administration.

7. Claims 30-38, 47-55, 63-66, and 68-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,391,303. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '303 patent claims oral co-administration of an antigen which can be a protein, a peptide, a carbohydrate, or a mucopolysaccharide, and a carrier having the formula recited in claims 2 and 11. The '303 patent specifically claims a carrier in claim 19 which differs from Applicants' claimed compound only in the length of the alkanoic acid group, i.e. butanoic vs. propanoic. The '303 patent's claimed generic formula embraces compounds having propanoic acid groups (see claim 2, column 17, line 15, and claim 11, column 18, line 15). It would have been obvious to one of ordinary skill in the art to form the claimed compositions of the '303 patent using a carrier having Applicants' claimed structure because Applicants' claimed compound is encompassed within the claimed formula of the '303 patent; because Applicants' claimed compound is a homolog of the compound specifically exemplified at claim 19 of the '303 patent differing only in the length of the alkanoic acid chain; and because Applicants' claimed compound is used to aid in the administration of the same types of drugs claimed by the '303 patent. The '303 patent does not claim administering the antigens and the carrier in combination with an excipient, diluent, or dosing vehicle. It would have been obvious to one of ordinary skill in the art to administer the antigens and the carrier claimed in the '303 patent in combination with an excipient, diluent, or dosing vehicle because excipients, diluents, and dosing vehicles are routinely used in the administration of therapeutic agents for ease of storage,

transport, measurement, and administration. The '303 patent does not claim administration in the form of a tablet, capsule, or liquid. It would have been obvious to one of ordinary skill in the art to administer the claimed compositions of the '303 patent in the form of a tablet, capsule, or liquid because these are routine forms used for oral administration of therapeutic compositions which are easy to formulate and administer.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

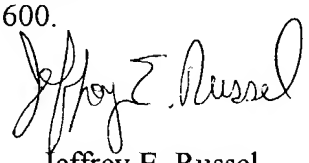
9. Claims 30-81 are rejected under 35 U.S.C. 103(a) as being obvious over Leone-Bay et al (U.S. Patent No. 5,643,957). Leone-Bay et al '957 teaches the oral administration of active agents in combination with modified amino acids having formula XLVI and optionally in combination with excipients, diluents, disintegrants, lubricants, plasticizers, colorants, dosing vehicles, water, 1,2-propane diol, and ethanol. Active agents include peptides, mucopolysaccharides, carbohydrates, lipids, human growth hormone, interferon, and low molecular weight heparin. The modified amino acids can also be in the form of a poly(amino acid) or polypeptide. See, e.g., column 6, line 55 - column 7, line 11, and column 21, lines 10-62. Leone-Bay et al '957 exemplifies a compound of formula VI at column 3 and claim 1 which differs from Applicants' claimed compound only in the length of the alkanoic acid group, i.e. butanoic vs. propanoic. Leone-Bay et al '957's generic formula embraces compounds having propanoic acid groups (see column 13, line 2). Leone-Bay et al '957 also does not teach parathyroid hormone as a biologically active peptide or hormone to be administered with the modified amino acids. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the compositions of Leone-Bay et al '957 using a compound having Applicants' claimed structure because Applicants' claimed compound is encompassed within the generic formula of Leone-Bay et al '957; because Applicants' claimed compound is a homolog of the compound specifically exemplified at column 3 and claim 1 of Leone-Bay et al '957 differing only in the length of the alkanoic acid chain; and because Applicants' claimed compound has only the activity to be expected from the disclosure of Leone-Bay et al '957. It would further have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer parathyroid hormone with the modified amino

acids of Leone-Bay et al '957 as discussed above because parathyroid hormone is a well-known biologically active peptide and hormone which is routinely administered in the art, and because the ability of the modified amino acids of Leone-Bay et al '957 to facilitate oral delivery of active agents is not dependent upon the identity of the active agents.

10. The Picciola article (Il Farmaco, Vol. 31, pages 655-664) is cite as art of interest, teaching at page 662, Table III, compound XXII, a homolog of the instant claimed compound. However, as the compounds of the Picciola article are described as being devoid of significant activity, there is no motivation under 35 U.S.C. 103 to form homologs of the compounds of the Picciola article.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
July 16, 2004